

### **REMARKS**

Applicants respectfully request entry of the Amendment and reconsideration of the claims. Please cancel claims 2-49 without prejudice and disclaimer. Applicants reserve the right to pursue the cancelled subject matter in one or more continuation or divisional applications.

Applicants have amended claim 1 to recite “[a] method of decreasing levels of interleukin-6 (IL-6) comprising administering pyridoxal-5’-phosphate or a pharmaceutically acceptable salt thereof.” Support for the amendment to claim 1 can be found at page 4, lines 22-30; page 39, lines 8-31; and Figures 1 and 2.

Applicants have added new claims 50-58. Support can be found throughout the application, including at page 3, lines 3-21; page 14, line 22 to page 15, line 15; page 19, line 8 to page 20, line 27; and page 21, lines 5-33.

Applicants respectfully request reconsideration and withdrawal of the objections to the claims and pending rejections under obviousness-type double patenting and 35 U.S.C. § 102(b).

### **Objections to the Claims**

The Examiner objects to claim 1 due to the fact that no subject/patient is provided for in the active step. Applicant has amended claim 1 to recite “[a] method of decreasing IL-6 comprising administering pyridoxal-5’-phosphate or a pharmaceutically acceptable salt thereof.” Applicant respectfully asserts that the language “to a subject in need thereof”, suggested by the Examiner for former claim 1, is not required in view of the amendment to claim 1. Applicant respectfully asserts that amended claim 1 also encompasses administering pyridoxal-5’-phosphate to cell cultures to decrease levels of IL-6 as exemplified at page 39, lines 8-31. Thus, the Examiner’s limitation of “to a subject in need thereof” is not appropriate for amended claim 1. In view of the foregoing. Applicant respectfully requests removal of the objections to the claim.

### **Rejection under 35 U.S.C. § 102(b)**

The Examiner rejects claim 1 under 35 U.S.C. § 102(b) as allegedly anticipated by Amadio et al. (*Neuropharmacology*, 42(4):489-501 (2002)). A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a

single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Applicant respectfully traverses this rejection.

In view of the amendment to claim 1, the Amadio et al. reference is no longer applicable. Amadio et al. do not disclose that pyridoxal-5'-phosphate decreases IL-6. For at least this reason, Amadio et al. do not disclose each and every element required to demonstrate anticipation. In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

### **Rejections under Obviousness-type Double Patenting**

The Examiner provisionally rejects claim 1 under the nonstatutory doctrine of obviousness-type double patenting over claims 1-12 of copending Application No. 11/739,920. The Examiner also provisionally rejects claim 1 under the nonstatutory doctrine of obviousness-type double patenting over claims 1-3, 6, 8-10, 13 and 15-17 of copending Application No. 11/564,192. Applicant respectfully traverses.

Applicant respectfully asserts that in view of amended claim 1, the claims in the copending applications cited by the Examiner are patentably distinct from a method of decreasing levels of IL-6. The Examiner cited the claims in the copending application to allegedly show a connection between atrial fibrillation and cell death. The Examiner has not established a connection between atrial fibrillation and levels of IL-6. As such, Applicant respectfully asserts that the instant claims are patentably distinct and requests removal of these provisional rejections.

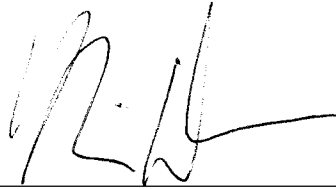
### **Summary**

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution

of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

MERCHANT & GOULD P.C.  
P.O. Box 2903  
Minneapolis, Minnesota 55402-0903  
(612) 332-5300



Date: June 13, 2008



---

Brian R. Dorn  
Reg. No. 57,395

BRD:RAD:sab